OCT - 5 2000

K002350

12.0 ReFacto Laboratory Standard 510(k) Summary of Safety and Effectiveness

1. Submitter: Genetics Institute Inc.
87 Cambridge Park Drive
Cambridge, Massachusetts 02140
Phone (617) 665-8737
Fax (617) 665-8876

Contact: Maryann Krane
Date of Preparation: June 1, 2000

2. Name of Device: Proprietary: ReFacto Laboratory Standard
Common: Secondary calibrator, generic
Classification: 864.7290 Factor Deficiency Test Class II Test, Qualitative and Quantitative Factor Deficiency
81 GGP

3. Predicate Device: Dade Calibration Reference Plasma K874940

4. Description of Device/Intended Use:

The ReFacto Laboratory Standard is composed of an assayed amount of ReFacto®, Antihemophilic Factor (Recombinant) in ~~human~~ albumin presented lyophilized in a single vial. The ReFacto Laboratory Standard is intended for laboratory use as a calibrated reference for coagulation assays monitoring FVIII:C levels, via either the one-stage clotting assay or the Chromogenic Substrate Assay, in patients with hemophilia A receiving ReFacto® ONLY.

5. Comparison to Predicate Device:

The predicate device (Dade® Calibration Reference Plasma) and the Genetics Institute device are similar as outlined below:

Comparison of Predicate Device and Genetics Institute Device

Feature	Dade	Genetics Institute
Intended Use	For in vitro diagnostic use as a calibrated normal reference plasma for use in coagulation assays.	For in vitro use as a calibrated reference for use in coagulation assays to measure FVIII:C levels in patients treated with ReFacto ONLY.
Format	Lyophilized	Lyophilized
Matrix	Human source matrix	Human source matrix
Coagulation Assays	One stage clotting assay; Chromogenic Substrate Assay	One stage clotting assay; Chromogenic Substrate Assay
Analytes	Multiple Factors including Factor VIII	ReFacto Factor VIII ONLY

Summary: The Refacto Laboratory Standard is substantially equivalent to the Dade Calibration Reference Plasma as a reference standard for use in coagulation assays.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 5 2000

Ms. Maryann Krane
Regulatory Affairs
Genetics Institute, Inc.
87 Cambridge, Massachusetts 02140

Re: K002350
Trade Name: ReFacto Laboratory Standard
Regulatory Class: II
Product Code: GGP
Dated: July 27, 2000
Received: August 2, 2000

Dear Ms. Krane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002350

Device Name: ReFacto Laboratory Standard
Genetics Institute, Inc

Indications For Use:

The ReFacto Laboratory Standard is intended for laboratory use as a calibrated reference for coagulation assays monitoring FVIII:C levels, with either the one-stage clotting assay or the Chromogenic Substrate Assay, in patients with hemophilia A receiving ReFacto®, Antihemophilic Factor (Recombinant) ONLY. It is not intended for patients with normal levels of FVIII:C or for patients receiving other factor VIII concentrates (plasma-derived or recombinant).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven C Maynard

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002350

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)